Substitute Bill No. 371

February Session, 2000

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## An Act Concerning The Classification And Regulation Of Drugs By The Department Of Consumer Protection And The Issuance Of A Temporary Permit To Practice Pharmacy.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

- Section 1. Subdivision (49) of section 21a-240 of the general statutes
- 2 is repealed and the following is substituted in lieu thereof:
- 3 (49) "Restricted drugs or substances" are the following substances
  - without limitation and for all purposes: Datura stramonium;
- 5 hyoscyamus niger; atropa belladonna, or the alkaloids atropine;
- 6 hyoscyamine; belladonnine; apatropine; or any mixture of these
- 7 alkaloids such as daturine, or the synthetic homatropine or any salts of
- 8 these alkaloids, except that any drug or preparation containing any of
- 9 the above-mentioned substances which is permitted by federal food
- 10 and drug laws to be sold or dispensed without a prescription or
- 11 written order shall not be a controlled substance; amyl nitrite; the
- 12 following volatile substances to the extent that said chemical
- 13 substances or compounds containing said chemical substances are
- sold, prescribed, dispensed, compounded, possessed or controlled or
- delivered or administered to another person with the purpose that said
- 16 chemical substances shall be breathed, inhaled, sniffed or drunk to
- 17 induce a stimulant, depressant or hallucinogenic effect upon the higher
- 18 functions of the central nervous system: Acetone; benzene; butyl
- 19 alcohol; butyl nitrate and its salts, isomers, esters, ethers or their salts;

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- 20 cyclohexanone; dichlorodifluoromethane; ether; ethyl acetate;
- 21 formaldehyde; hexane; isopropanol; methanol; methyl cellosolve
- 22 acetate; methyl ethyl ketone; methyl isobutyl ketone; nitrous oxide;
- 23 pentochlorophenol; toluene; toluol; trichloroethane; trichloroethylene;
- 24 1,4 butanediol.
- Sec. 2. Subsection (k) of section 21a-106 of the general statutes is
- 26 repealed and the following is substituted in lieu thereof:
- 27 (k) If it is a [drug sold at retail for use by man and contains any
- 28 quantity of amidopyrine, barbituric acid, cinchophen,
- 29 bishydroxycoumarin, dinitrophenol, methylparafynol, thiouracil or
- 30 thyroid, or any derivative of any of these substances, or (1) is a habit-
- 31 forming drug to which subsection (d) of this section applies; or (2)
- 32 because of its toxicity or other potentiality for harmful effect, or the
- 33 method of its use, or the collateral measures necessary to its use, is not
- 34 safe for use except under the supervision of a practitioner licensed by
- 35 law to administer such drug; or (3) is limited by an effective
- 36 application under section 21a-111 to use under the professional
- 37 supervision of a practitioner licensed by law to administer such drug,
- 38 unless it is sold on a written, oral or electronically-transmitted
- 39 prescription of a practitioner licensed by law to administer such drug;
- 40 and its label bears the name and place of business of the seller, the
- 41 serial number and date of such prescription and the name of such
- 42 practitioner] <u>legend drug, as defined in subdivision (14) of section 20-</u>
- 43 571, as amended by this act, that is not administered, dispensed,
- 44 prescribed or otherwise possessed or distributed in accordance with
- 45 <u>federal and state laws and regulations.</u>
- Sec. 3. Section 20-617 of the general statutes, as amended by public
- 47 act 99-49 and section 38 of public act 99-175, is repealed and the
- 48 following is substituted in lieu thereof:
- Each pharmacist shall include on the label of each prescription
- 50 container: (1) The quantity of prescribed drug placed in such container,
- 51 in addition to any other information required by law; and (2) a

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- 52 prominently printed expiration date <u>based on the manufacturer's</u>
- 53 <u>recommended conditions of use and storage</u> that can be read and
- understood by the ordinary individual. [under customary conditions
- of purchase, use and storage based on the manufacturer's
- recommended guidelines. In the absence of data to the contrary, the
- 57 The expiration date required pursuant to subdivision (2) of this section
- 58 shall be no later than the expiration date determined by the
- 59 manufacturer.
- Sec. 4. Subsection (l) of section 21a-249 of the general statutes is
- 61 repealed and the following is substituted in lieu thereof:
- 62 (l) Any pharmacy may transfer prescriptions for controlled
- 63 substances included in schedules III, IV and V to any other pharmacy
- 64 in accordance with the requirements set forth in [21 CFR 1306.26] the
- 65 federal Controlled Substances Act 21 USC 801 et seq. and the
- 66 <u>regulations promulgated thereunder</u>, as from time to time amended.
- 67 Sec. 5. Subdivisions (13) and (14) of section 20-571 of the general
- 68 statutes, as amended by section 6 of public act 99-175, are repealed and
- 69 the following is substituted in lieu thereof:
- 70 (13) "Legend device" means a device that is required by applicable
- 71 federal or state law to be dispensed pursuant only to a prescription or
- 72 is restricted to use by prescribing practitioners only or that, under
- 73 federal law, is required to bear either of the following legends: (A)
- 74 ["RX ONLY IN ACCORDANCE WITH GUIDELINES ESTABLISHED
- 75 IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT."] "RX
- 76 ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN
- 77 THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B)
- 78 "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE FOR USE BY
- 79 OR ON THE ORDER OF A LICENSED VETERINARIAN.";
- 80 (14) "Legend drug" means a drug that is required by any applicable
- 81 federal or state law to be dispensed pursuant only to a prescription or
- 82 is restricted to use by prescribing practitioners only, or means a drug
- 83 that, under federal law, is required to bear either of the following

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- 84 legends: (A) ["RX ONLY IN ACCORDANCE WITH GUIDELINES
- 85 ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC
- 86 ACT."] "RX ONLY" IN ACCORDANCE WITH GUIDELINES
- 87 ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC
- 88 ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG
- 89 FOR USE BY OR ON THE ORDER OF A LICENSED
- 90 VETERINARIAN.".
- 91 Sec. 6. Section 21a-318 of the general statutes, as amended by section
- 92 50 of public act 99-175, is repealed and the following is substituted in
- 93 lieu thereof:
- An application for registration pursuant to this chapter shall be
- 95 made upon a form provided by the Commissioner of Consumer
- 96 Protection and shall be accompanied by a fee of [twenty-five] ten
- 97 dollars for [biennial licensure] annual registration, except that a
- 98 practitioner who obtains such registration pursuant to the
- 99 practitioner's employment with a municipality, this state or the federal
- government shall not be required to pay the fee.
- Sec. 7. Section 20-579 of the general statutes, as amended by section
- 102 14 of public act 99-175, is repealed and the following is substituted in
- 103 lieu thereof:
- 104 (a) The commission may refuse to authorize the issuance of a
- temporary permit to practice pharmacy, may refuse to authorize the
- 106 issuance or renewal of a license to practice pharmacy, a license to
- operate a pharmacy or a registration of a pharmacy intern or pharmacy
- technician, and may revoke or suspend a license or temporary permit
- 109 to practice pharmacy, a license to operate a pharmacy, or a registration
- of a pharmacy intern or a pharmacy technician, and may assess a civil
- penalty of up to one thousand dollars or take other action permitted in
- subdivision (7) of section 21a-7 if the applicant or holder of the license,
- 113 temporary permit or registration: (1) Has violated a statute or
- regulation relating to drugs, devices or the practice of pharmacy of this
- state, any state of the United States, the United States, the District of

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Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (2) has been convicted of violating any criminal statute relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (3) has been disciplined by, or is the subject of pending disciplinary action or an unresolved complaint before, the duly authorized pharmacy disciplinary agency of any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (4) has been refused a license or registration or renewal of a license or registration by any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction based on grounds that are similar to grounds on which Connecticut could refuse to issue or renew such a license or registration; (5) has illegally possessed, diverted, sold or dispensed drugs or devices; (6) abuses or excessively uses drugs, including alcohol; (7) has made false, misleading or deceptive representations to the public or the commission; (8) has maintained exclusive telephone lines to, has maintained exclusive electronic communication with, or has exclusive access to computers located in offices of prescribing practitioners, nursing homes, clinics, hospitals or other health care facilities; (9) has substituted drugs or devices except as permitted in section 20-619, as amended by section 39 of public act 99-175; (10) has accepted, for return to regular stock, any drug already dispensed in good faith or delivered from a pharmacy, and exposed to possible and uncontrolled contamination or substitution; (11) has split fees for professional services, including a discount or rebate, with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other health care facility; (12) has entered into an agreement with a prescribing practitioner or an administrator or owner of a nursing

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home, hospital or other health care facility for the compounding or dispensing of secret formula or coded prescriptions; (13) has performed or been a party to a fraudulent or deceitful practice or transaction; (14) has presented to the commission a diploma, license or certificate illegally or fraudulently obtained, or obtained from a college or school of pharmacy not approved by the commission; (15) has performed incompetent or negligent work; (16) has falsified a continuing education document submitted to the commission or department or a certificate retained in accordance with the provisions of subsection (d) of section 20-600, as amended by section 29 of public act 99-175; (17) has permitted a person not licensed to practice pharmacy in this state to practice pharmacy in violation of section 20-605, as amended by section 31 of public act 99-175, to use a pharmacist license or pharmacy display document in violation of section 20-608, as amended by section 34 of public act 99-175, or to use words, displays or symbols in violation of section 20-609; or (18) has failed to maintain the entire pharmacy premises, its components and contents in a clean, orderly and sanitary condition.

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(b) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke or suspend a license or temporary permit to practice pharmacy, a license to operate a pharmacy, or a registration of a pharmacy intern or a pharmacy technician, or take other action permitted in subdivision (7) of section 21a-7 if the commission determines that the applicant or holder of the license, temporary permit or registration has a condition including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of pharmacy, operation of a pharmacy or activities as a pharmacy intern or pharmacy technician, provided the commission may not, in taking action against a license, temporary permit or registration holder on the

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- basis of such a condition, violate the provisions of section 46a-73 or 42
- 186 USC Section 12132 of the federal Americans with Disabilities Act.
- Sec. 8. Section 20-590 of the general statutes is amended by adding subsections (c) and (d) as follows:
- 189 (NEW) (c) The Department of Consumer Protection shall, upon 190 authorization of the commission, issue a temporary permit to practice 191 pharmacy to an individual who: (1) Practices under the direct 192 supervision of a licensed pharmacist; (2) has an application for 193 reciprocity on file with the commission; (3) is a licensed pharmacist in 194 good standing in a state or jurisdiction from which such state's 195 pharmacy board or commission of pharmacy grants similar reciprocal 196 privileges to pharmacists licensed in this state; and (4) has no actions 197 pending against such individual's license with any state's pharmacy 198 board or commission of pharmacy.
- (NEW) (d) A temporary permit to practice pharmacy shall expire at the time the individual with the temporary permit is licensed as a pharmacist in this state, or not later than six months from the date of issuance of such temporary permit. The Department of Consumer Protection shall not issue more than one temporary permit to practice pharmacy to an individual.
- Sec. 9. Section 20-601 of the general statutes, as amended by section 30 of public act 99-175, is repealed and the following is substituted in lieu thereof:
- The department shall collect the following nonrefundable fees:
- 209 (1) The fee for issuance of a pharmacist license [shall be] <u>is</u> one 210 hundred dollars, payable at the date of application for the license.
- 211 (2) The fee for applying to take the pharmacist license examination 212 required in section 20-590, as amended by section 18 of public act 99-213 175, and as amended by this act, and in section 20-591, as amended by 214 section 19 of public act 99-175, [shall be] is one hundred fifty dollars,

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- 215 payable at the date of application for the pharmacist license.
- 216 (3) The fee for renewal of a pharmacist license [shall be] is the
- 217 professional services fee for class A, as defined in section 33-182l.
- 218 Before the commission grants a license to an applicant who has not
- 219 held a license authorized by the commission within five years of the
- 220 date of application, the applicant shall pay the fees required in
- 221 subdivisions (1) and (2) of this section.
- 222 (4) The fee for issuance of a pharmacy license [shall be] is six
- 223 hundred dollars.
- 224 (5) The fee for renewal of a pharmacy license [shall be] is one
- 225 hundred fifty dollars.
- 226 (6) The late fee for an application for renewal of a license to practice
- 227 pharmacy, a pharmacy license or a permit to sell nonlegend drugs
- 228 [shall be] is the amount set forth in section 21a-4, as amended by
- section 4 of public act 99-194.
- 230 (7) The fee for notice of a change in officers or directors of a
- 231 corporation holding a pharmacy license [shall be] is thirty dollars for
- each pharmacy license held. A late fee for failing to give such notice
- 233 within ten days of the change [shall be] is twenty-five dollars in
- addition to the fee for notice.
- 235 (8) The fee for filing notice of a change in name, ownership or
- 236 management of a pharmacy [shall be] is forty-five dollars. A late fee
- for failing to give such notice within ten days of the change [shall be] is
- 238 twenty-five dollars in addition to the fee for notice.
- 239 (9) The fee for application for registration as a pharmacy intern
- 240 [shall be] is thirty dollars.
- 241 (10) The fee for application for a permit to sell nonlegend drugs
- [shall be] <u>is</u> seventy dollars.
- 243 (11) The fee for renewal of a permit to sell nonlegend drugs [shall

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- be] <u>is</u> fifty dollars.
- 245 (12) The late fee for failing to notify the commission of a change of
- 246 ownership, name or location of the premises of a permit to sell
- 247 nonlegend drugs within five days of the change [shall be] is ten
- 248 dollars.
- 249 (13) The fee for issuance of a nonresident pharmacy certificate of
- 250 registration [shall be] <u>is</u> six hundred dollars.
- 251 (14) The fee for renewal of a nonresident pharmacy certificate of
- registration [shall be] is one hundred fifty dollars.
- 253 (15) The fee for application for registration as a pharmacy technician
- 254 [shall be] is fifty dollars.
- 255 (16) The fee for renewal of a registration as a pharmacy technician
- 256 [shall be] <u>is</u> twenty-five dollars.
- 257 (17) The fee for issuance of a temporary permit to practice pharmacy
- is one hundred dollars.
- Sec. 10. Section 20-605 of the general statutes, as amended by section
- 260 31 of public act 99-175, is repealed and the following is substituted in
- 261 lieu thereof:
- No individual may engage in the practice of pharmacy unless the
- 263 individual holds a current license or temporary permit to practice
- 264 pharmacy issued by the department.
- Sec. 11. Section 20-607 of the general statutes, as amended by section
- 266 33 of public act 99-175, is repealed and the following is substituted in
- 267 lieu thereof:
- 268 Each person practicing as a pharmacist, pharmacy intern or
- 269 pharmacy technician shall at all times have available for inspection by
- 270 an inspector of the department a current certificate of license or
- 271 <u>temporary permit</u> to practice pharmacy or a current registration to act

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- as a pharmacy intern or pharmacy technician.
- Sec. 12. Section 20-608 of the general statutes, as amended by section
- 274 34 of public act 99-175, is repealed and the following is substituted in
- 275 lieu thereof:
- A pharmacist who permits such pharmacist's certificate of license,
- 277 <u>temporary permit</u> or display document to be used by an unlicensed
- 278 person for unlawful use shall be fined one hundred dollars and shall
- be subject to other disciplinary proceedings within the authority of the
- 280 commission.
- Sec. 13. Subsection (a) of section 20-613 of the general statutes, as
- amended by section 35 of public act 99-175, is repealed and the
- 283 following is substituted in lieu thereof:
- 284 (a) Except as provided in subsections (b) and (d) of this section, a
- drug or a legend device may be dispensed pursuant to a prescription
- only in a pharmacy or institutional pharmacy by a pharmacist or by a
- 287 pharmacy intern when acting under the direct supervision of a
- 288 pharmacist, or by an individual holding a temporary permit.

GL Committee Vote: Yea 14 Nay 0 JFS

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